REMARKS

Claims 7, 9, 28 and 29 are pending, and all of the pending claims are rejected.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejects claims 7, 9, 28 and 29 as not properly enabled even in view of the Declaration of Dr. Sean Mason. Applicants previously explained that the data presented in the Declaration demonstrate that a CDCP1 specific antibody mediates lysis of ovarian cancer cells *in vitro* and drastically decreases tumor growth or establishment of *in vivo* cells that express CDCP1. According to the Examiner, the data presented in the Declaration demonstrate that a full length IgG antibody is capable of inducing cell lysis *in vitro* when exposed to a crude separation of PBMCs and that the full length antibody is capable of reducing tumor burden of a mouse model of melanoma *in vivo*. The Examiner says that this data does not support treating ovarian cancer since it is unclear how the mouse model of melanoma relates to treating ovarian cancer (e.g. different cell types, different organ systems, and different mechanisms). Further, regarding claim 28, it is allegedly unclear whether an antibody fragment would work at all.

Regarding the *in vivo* model used

Applicants clarify that the *in vivo* model used to obtain the information presented in the Declaration of Dr. Sean Mason pursuant to 37 C.F.R. 1.132 was the B16-F10 mouse model of melanoma. The B16-F10 mouse model is a widely used model for studying many aspects of cancer biology and therapeutics in a solid tumor. The B16-F10 mouse model is a well accepted model where the melanomas aggressively progress within a dynamic microenvironment containing in addition to tumor cells, stroma cells and components such as fibroblasts, immune cells, vascular cells, extracellular matrix (ECM) and extracellular molecules. Applicants respectfully refer the Examiner to information from the company that supplies the cells available at http://www.caliperls.com/products/b16f101ucg5-biowarereg-cell-line-pn-119269.htm , a copy of which is enclosed herewith as Exhibit A. The information indicates that

> [T]he B16-F10-luc-G5 Bioware® Cell Line (P/N 119269) may be used in vivo to establish subcutaneous tumor models and experimental metastasis model (lung colonization after intravenous injection). Bioluminescent imaging detected tumor cells

throughout the experiment; measurable tumors may be measured by califper within two weeks after the subcutaneous injection. In vivo photon counts of lung metastasis after i.v. injection correlated to mean number of lesions on the surface of the lung. Ex vivo imaging confirmed metastases in pancreas, liver, kidneys, and adipose tissue in some mice after the intravenous cell injection.

The cell line was engineered to express CDCP1 before it was administered to the mice in the study. Thus the model provides cancer cells that express on their surface a antigen CDCP1 specific to ovarian cancer. This is an approximation of a patient with the disease, as are all animal models, and the approach has accepted scientific merit. As such, Applicants submit that a mouse model of melanoma relates to and is predictive of success in treating ovarian cancer. The data already presented provides evidence that tumor growth was drastically decreased, indicating that the antibodies are useful in treating human disease.

Regarding antibody fragments

Applicants submit that an antibody fragment would be expected to successfully treat ovarian cancer if a full length antibody is successful. While there may be some differences in half-life between full length antibodies and antibody fragments, Applicants submit that those of ordinary skill in the art appreciate ways of dealing with these practical differences. For example, an antibody fragment may be pegylated (a conjugate formed between an antibody fragment and polyethylene glycol). When an antibody fragment is pegylated, it generally has the same or a similar half life to that of a full length antibody. Furthermore, antibody fragments are known to be useful such that some companies are solely dedicated to developing the technology. As such, Applicants submit that an antibody fragment would be expected to provide the same *in vivo* response.

Rejection under 35 U.S.C. 102

The Examiner rejects claims 7, 9 and 29 as allegedly anticipated by Schweifer *et al.*, U.S. Publication 2002/0142003. According to the Examiner, Schweifer *et al.* teach monoclonal antibodies that bind B345 for therapy and diagnosis of cancer, and the sequence of B345 is allegedly 99.8% identical to the sequence of SEQ ID NO: 1 of the present claims. The present claim language encompasses antibodies that would bind to any of SEQ ID NO: 1 because of the "comprising" language.

The United States patent law is clear that ***a reference must enable the teachings that it alleges in order to serve as a proper prior art reference.*** Applicants respectfully submit that Schweifer *et al.* do not enable a method to treat ovarian cancer. They present absolutely no data demonstrating clinical efficacy of an antibody to B345 for any cancer. Stated differently, one of ordinary skill in the art would find no reasonable expectation of succeeding in treating ovarian cancer from the teachings of Schweifer *et al.*

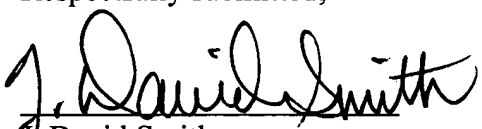
Fees

No additional fees are believed to be necessitated by this amendment. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted that the claims are in condition for allowance. In the event that there are any questions that can be resolved by way of telephone, the Examiner is respectfully urged to telephone the undersigned at the telephone number indicated below.

Respectfully submitted,



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Date: June 27, 2008

Enclosure: Appendix A